

Material Code M0636

Revision 00

Type PP
 Brand name 100-GB06
 Supplier INEOS

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Ethylene Oxide	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	US Pharmacopoeia 29, <88>

Main Regulatory Compliances:

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
Food Contact	YES	Annex IV, Regulation (EU) 10/2011/ FDA 21 CFR 177.1520 and 21 CFR 170-189
European Directive (2004/12/EC) Packaging and Packaging Waste	YES	-
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Directive 2012/19/UE - WEEE	YES	-
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	<1 ppm
TSE / BSE	YES	no risk manufactured from starting substances or contain additives which may be of genetically modified organism's origin.
US Pharmacopoeia	YES	
European Directive (EC 1907/2006) REACH	YES	-
MSDS	YES	-

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Extrusion	YES	-	-
Injection	YES	-	-
Density	<1	-	-
Color	off-white	-	-
Melt Flow Rate	6 g/ 10min	ISO 1133-1	230°C/ 2.16 kg
Modulus of Elasticity / Young modulus	1450 MPa	ISO 178	-
Tensile Strength at Yield	34 MPa	ISO 527-1/ -2	-

R&D Validation	FRA	QA/RA Validation	CGI
Date	25-08-2017	Date	13-09-2017

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promepla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promepla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.